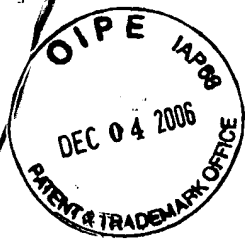


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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/516,450 Confirmation No.: 2998
Applicant : Gary E. GILBERT and JIALAN SHI
Filed : December 2, 2004
Title : METHOD AND COMPOSITION FOR INHIBITING OR
SLOWING BLOOD COAGULATION
Group Art Unit : 1653
Examiner : Desai, Anand U.
Atty. Docket No. : US 1418/04
Date : December 4, 2006

**SECOND
INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56 and 1.97-1.98, Applicant(s) note(s) herewith various reference(s) for the Examiner's consideration. The references include, *inter alia*, those cited on pages 45-54 of the application. The Examiner's attention is also directed to co-pending application S.N. 10/562,269, filed December 28, 2005 (please see attached corresponding Intn'l Appl. No. PCT/US/2004/017431). The Examiner is respectfully

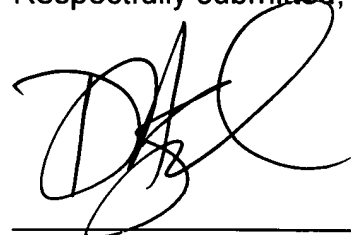
requested to review and officially consider and make the reference(s) of record before issuing the next Office Action in connection with this case.

A completed form 1449B/PTO listing the reference(s) thereon is enclosed herewith. (Only the copy(ies) of foreign patent documents and non-patent literature, if applicable, is/are enclosed.) The Examiner is respectfully requested to return an initialed copy of form 1449B/PTO along with the next communication in connection with this case.

It is believed that no fee is due for this submission. Should that determination be incorrect, however, the Examiner is hereby authorized to charge any deficiencies, or credit any overpayment, to our Deposit Account No. 01-0433, and notify the undersigned in due course.

Should the Examiner have any questions or wish to discuss further this matter, please contact the undersigned at the telephone number provided below.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'D. Agarwal', written over a horizontal line.

DINESH AGARWAL
Attorney for Applicant(s)
Reg. No. 31,809

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Alexandria, Virginia 22312
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|--------------------------------|-----------------------|---|----------------|
| | | Hvarregaard J, Andersen MH, Berglund L, Rasmussen JT, Petersen TE. Characterization of glycoprotein PAS-6/7 from membranes of bovine milk fat globules. Eur J Biochem. 1996;240:628-636. | |
| | | Stubbs J, Lekutis C, Singer K, et al. cDNA cloning of a mouse mammary epithelial cell surface protein reveals the existence of epidermal growth factor-like domains linked to factor VIII-like sequences. Proc Natl Acad Sci, USA. 1990;87:8417-8421. | |
| | | Couto JR, Taylor MR, Godwin SG, Ceriani RL, Peterson JA. Cloning and sequence analysis of human breast epithelial antigen BA46 reveals an RGD cell adhesion sequence presented on an epidermal growth factor-like domain. DNA Cell Biol. 1996;15:281-286. | |
| | | Andersen MH, Berglund L, Rasmussen JT, Petersen TE. Bovine PAS-6/7 binds $\alpha_v\beta_5$ integrin and anionic phospholipids through two domains. Biochem. 1997;36:5441-5446. | |
| | | Taylor MR, Couto JR, Scallan CD, Ceriani RL, Peterson JA. Lactadherin (formerly BA46), a membrane-associated glycoprotein expressed in human milk and breast carcinomas, promotes Arg-Gly-Asp (RGD)-dependent cell adhesion. DNA Cell Biol. 1997;16:861-869. | |
| | | Andersen MH, Graversen H, Fedosov SN, Petersen TE, Rasmussen JT. Functional analyses of two cellular binding domains of bovine lactadherin. Biochem. 2000;39:6200-6206. | |
| | | Butler JE, Pringnitz DJ, Martens CL, Crouch N. Bovine-associated mucoprotein: I. Distribution among adult and fetal bovine tissues and body fluids. Differentiation. 1980;17:31-40. | |
| | | Newburg DS, Peterson JA, Ruiz-Palacios GM, et al. Role of human-milk lactadherin in protection against symptomatic rotavirus infection. Lancet. 1998;351:1160-1164. | |
| | | Peterson JA, Couto JR, Taylor MR, Ceriani RL. Selection of tumor-specific epitopes on target antigens for radioimmunotherapy of breast cancer. Cancer Res. 1995;55:5847s-5851s. | |
| | | Haggqvist B, Naslund J, Sletten K, et al. Medin: an integral fragment of aortic smooth muscle cell-produced lactadherin forms the most common human amyloid. Proc Natl Acad Sci U S A. 1999;96:8669-8674. | |

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| | | Ensslin M, Calvete JJ, Thole HH, et al. Identification by affinity chromatography of boar sperm membrane- associated proteins bound to immobilized porcine zona pellucida. Mapping of the phosphorylethanolamine-binding region of spermadhesin AWN. Biol Chem Hoppe Seyler. 1995;376:733-738. | |
| | | Arai M, Scandella D, Hoyer L. Molecular basis of factor VIII inhibition by human antibodies. Antibodies that bind to the factor VIII light chain prevent the interaction of factor VIII with phospholipid. J Clin Invest. 1989;83:1978-1984. | |
| | | Foster PA, Fulcher CA, Houghten RA, Zimmerman TS. Synthetic factor VIII peptides with amino acid sequences contained within the C2 domain of factor VIII inhibit factor VIII binding to phosphatidylserine. Blood. 1990;75:1999-2004. | |
| | | Ortel T, Devore-Carter D, Quinn-Allen M, Kane W. Deletion analysis of recombinant human factor V: Evidence for a phosphatidylserine binding site in the second C-type domain. J Biol Chem. 1992;267:4189-4198. | |
| | | Gilbert GE, Furie BC, Furie B. Binding of human factor VIII to phospholipid vesicles. J Biol Chem. 1990;265:815-822. | |
| | | Gilbert GE, Drinkwater D, Barter S, Clouse SB. Specificity of phosphatidylserine-containing membrane binding sites for factor VIII: Studies with model membranes supported by glass microspheres (Lipospheres). J Biol Chem. 1992;267:15861-15868. | |
| | | Gilbert GE, Drinkwater D. Specific membrane binding of factor VIII is mediated by O-phospho-L-serine, a moiety of phosphatidylserine. Biochem. 1993;32:9577-9585. | |
| | | Comfurius P, Smeets EF, Willems GM, Bevers EM, Zwaal RFA. Assembly of the prothrombinase complex on lipid vesicles depends on the stereochemical configuration of the polar headgroup of phosphatidylserine. Biochem. 1994;33:10319-10324. | |
| | | Gilbert GE, Arena AA. Phosphatidylethanolamine induces high affinity binding sites for factor VIII on membranes containing phosphatidyl-L-serine. J Biol Chem. 1995;270:18500-18505. | |
| | | Gilbert GE, Arena AA. Unsaturated phospholipid acyl chains are required to constitute membrane binding sites for factor VIII. Biochem. 1998;37:13526-13535. | |

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|-----------------------------------|--------------------------|---|----------------|
| | | Pratt KP, Shen BW, Takeshima K, et al. Structure of the C2 domain of human factor VIII at 1.5 angstrom resolution. Nature. 1999;402:439-442. | |
| | | Macedo-Ribeiro S, Bode W, Huber R, et al. Crystal structures of the membrane-binding C2 domain of human coagulation factor V. Nature. 1999;402:434-439. | |
| | | Kim SW, Quinn-Allen MA, Camp JT, et al. Identification of functionally important amino acid residues within the C2-domain of human factor V using alanine-scanning mutagenesis. Biochem. 2000;39:1951-1958. | |
| | | Peterson JA, Patton S, Hamosh M. Glycoproteins of the human milk fat globule in the protection of the breast-fed infant against infections. Biol Neonate. 1998;74:143-162. | |
| | | Tait JF, Gibson D, Fujikawa K. Phospholipid binding properties of human placental anticoagulant protein-1, a member of the lipocortin family. J Biol Chem. 1989;264:7944-7949. | |
| | | Crompton MR, Moss SE, Crompton MJ. Diversity in the lipocortin/calpactin family. Cell. 1988;55:1-3. | |
| | | Swairjo MA, Concha NO, Kaetzel MA, Dedman JR, Seaton BA. Ca ²⁺ -bridging mechanism and phospholipid head group recognition in the membrane-binding protein annexin V. Nat Struct Biol. 1995;2:968-974. | |
| | | Tait JF, Sakata MS, McMullen BA, et al. Placental anticoagulant proteins: Isolation and comparative characterization of four members of the lipocortin family. Biochem. 1988;27:6268-6276. | |
| | | Gilbert GE, Arena AA. Activation of the factor VIIIa-factor IXa enzyme complex of blood coagulation by membranes containing phosphatidyl-L-serine. J Biol Chem. 1996;271:11120-11125. | |
| | | Bangham AD, Standish MM, Watkins JC. Diffusion of univalent ions across the lamellae of swollen phospholipids. J Mol Biol. 1965;13:238-252. | |

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|-----------------------------------|--------------------------|--|----------------|
| | | Johnson SM, Bangham AD, Hill MW, Korn ED. Single bilayer liposomes. Biochim Biophys Acta. 1971;233:820-826. | |
| | | Hope MJ, Bally MB, Webb G, Cullis PR. Production of large unilamellar vesicles by a rapid extrusion procedure. Characterization of size distribution, trapped volume and ability to maintain a membrane potential. Biochim Biophys Acta. 1985;812:55-65. | |
| | | Chen P, Toribara T, Warner H. Anal Chem. 1956;28:1756-1758. | |
| | | Neuenschwander PF, Morrissey JH. Deletion of the membrane anchoring region of tissue factor abolishes autoactivation of factor VII but not cofactor function. Analysis of a mutant with a selective deficiency in activity. J Biol Chem. 1992;267:14477-14482. | |
| | | Lollar P, Fass DN. Inhibition of activated porcine factor IX by dansyl-glutamyl-glycyl-arginyl-chloromethylketone. Arch Biochem Biophys. 1984;233:438-446. | |
| | | Gilbert GE, Sims PJ, Wiedmer T, et al. Platelet-derived microparticles express high affinity receptors for factor VIII. J Biol Chem. 1991;266:17261-17268. | |
| | | Govers-Riemslog JW, Janssen MP, Zwaal RF, Rosing J. Prothrombin activation on dioleoylphosphatidylcholine membranes. Eur J Biochem. 1994;220:131-138. | |
| | | Andree HA, Stuart MC, Hermens WT, et al. Clustering of lipid-bound annexin V may explain its anticoagulant effect. J Biol Chem. 1992;267:17907-17912. | |
| | | Huang C, Mason J. Geometric packing constraints in egg phosphatidylcholine vesicles. Proc Natl Acad Sci, USA. 1978;75:308-310. | |
| | | Andree H, Reutelingsperger C, Hauptmann R, et al. Binding of vascular anticoagulant a (VACa) to planar phospholipid bilayers. J Biol Chem. 1990;265:4923-4928. | |

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|-----------------------------------|--------------------------|---|----------------|
| | | Ueno M, Tanford C, Reynolds JA. Phospholipid vesicle formation using nonionic detergents with low monomer solubility. Kinetic factors determine vesicle size and permeability. Biochem. 1984;23:3070-3076. | |
| | | Mann KG, Nesheim ME, Church WR, Haley P, Krishnaswamy S. Surface-dependent reactions of the vitamin K-dependent enzyme complexes. Blood. 1990;76:1-16. | |
| | | Freyssinet JM, Gauchy J, Cazenave JP. The effect of phospholipids on the activation of protein C by the human thrombin-thrombomodulin complex. Biochem J. 1986;238:151-157. | |
| | | Suzuki K, Stenflo J, Dahlback B, Teodorsson B. Inactivation of human coagulation factor V by activated protein C. J Biol Chem. 1983;258:1914-1920. | |
| | | Connor J, Schroit A. Transbilayer movement of phosphatidylserine in erythrocytes: Inhibition of transport and preferential labeling of a 31000-dalton protein by sulfhydryl reactive reagents. Biochem. 1988;27:848-851. | |
| | | Connor J, Bucana C, Fidler IJ, Schroit AJ. Differentiation-dependent expression of phosphatidylserine in mammalian plasma membranes: Quantitative assessment of outer-leaflet lipid by prothrombinase complex formation. Proc Natl Acad Sci USA. 1989;86:3184-3188. | |
| | | Fadok VA, Voelker DR, Campbell PA, et al. Exposure of phosphatidylserine on the surface of apoptotic lymphocytes triggers specific recognition and removal by macrophages. J Immunol. 1992;148:2207-2216. | |
| | | Bervers E, Comfurius P, Zwaal R. Changes in membrane phospholipid distribution during platelet activation. Biochim Biophys Acta. 1983;736:57-66. | |
| | | van Heerde WL, Poort S, van 't Veer C, Reutelingsperger CP, de Groot PG. Binding of recombinant annexin V to endothelial cells: effect of annexin V binding on endothelial-cell-mediated thrombin formation. Biochem J. 1994;302 (Pt 1):305-312. | |
| | | London F, Ahmad SS, Walsh PN. Annexin V inhibition of factor IXa-catalyzed factor X activation on human platelets and on negatively-charged phospholipid vesicles. Biochem. 1996;35:16886-16897. | |

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| | | Nimpf J, Bevers EM, Bomans PH, et al. Prothrombinase activity of human platelets is inhibited by beta 2-glycoprotein-I. Biochim Biophys Acta. 1986;884:142-149. | |
| | | Mori T, Takeya H, Nishioka J, Gabazza EC, Suzuki K. beta 2-Glycoprotein I modulates the anticoagulant activity of activated protein C on the phospholipid surface. Thromb Haemost. 1996;75:49-55. | |
| | | McNeil HP, Simpson RJ, Chesterman CN, Krilis SA. Anti-phospholipid antibodies are directed against a complex antigen that includes a lipid-binding inhibitor of coagulation: beta 2-glycoprotein I (apolipoprotein H). Proc Natl Acad Sci U S A. 1990;87:4120-4124. | |
| | | Takeya H, Mori T, Gabazza EC, et al. Anti-beta2-glycoprotein I (beta2GPI) monoclonal antibodies with lupus anticoagulant-like activity enhance the beta2GPI binding to phospholipids. J Clin Invest. 1997;99:2260-2268. | |
| | | Bancsi LF, van der Linden IK, Bertina RM. Beta 2-glycoprotein I deficiency and the risk of thrombosis. Thromb Haemost. 1992;67:649-653. | |
| | | Ceriani RL, Sasaki M, Sussman H, Wara WM, Blank EW. Circulating human mammary epithelial antigens in breast cancer. Proc Natl Acad Sci U S A. 1982;79:5420-5424. | |
| | | Enoch HG, Strittmatter P. Formation of properties of 1000-Å-diameter, single-bilayer phospholipid vesicles. Proceeding of the National Academy of Sciences, USA 1979;76:145-149. | |
| | | Hanayama R, Tanaka M, Miwa K, Shinohara A, Iwamatsu A, Nagata S. Identification of a factor that links apoptotic cells to phagocytes. Nature 2002;417(6885):182-7. | |
| | | Shi J, Gilbert GE. Lactadherin inhibits enzyme complexes of blood coagulation by competing for phospholipid binding sites. Blood 2003;101(7):2628-36. | |
| | | Bardelle C, Furie B, Furie BC, Gilbert GE. Kinetic Studies of Factor VIII Binding to Phospholipid Membranes Indicate a Complex Binding Process. J. Biol. Chem. 1993;268:8815-24. | |

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| First Named Inventor | Gary E. GILBERT et al. |
| Group Art Unit | 1653 |
| Examiner Name | DESAI, Anand U. |
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|--------------------------------|-----------------------|---|----------------|
| | | Gilbert GE, Kaufman RJ, Arena AA, Miao H, Pipe SW. Four hydrophobic amino acids of the factor VIII C2 domain are constituents of both the membrane-binding and von Willebrand factor-binding motifs. J Biol Chem 2002;277(8):6374-81. | |
| | | Dachary-Prigent J, Freyssinet JM, Pasquet JM, Carron JC, Nurden AT. Annexin V as a probe of aminophospholipid exposure and platelet membrane vesiculation: a flow cytometry study showing a role for free sulfhydryl groups. Blood 1993;81(10):2554-65. | |
| | | Alberio L, Safa O, Clemetson KJ, Esmon CT, Dale GL. Surface expression and functional characterization of alpha-granule factor V in human platelets: effects of ionophore A23187, thrombin, collagen, and convulxin. Blood 2000;95(5):1694-702. | |
| | | Zwaal R, Comfurius P, van Deenen L. Membrane asymmetry and blood coagulation. Nature 1977;268:358-360. | |
| | | Bervers E, Comfurius P, Van Rijn J, Hemker H, Zwaal R. Generation of Prothrombin-Converting Activity and the Exposure of Phosphatidylserine at the Outer Surface of Platelets. Eur. J. Biochem. 1982;122:429-436. | |
| | | Seigneuret M, Devaux PF. ATP-dependent asymmetric distribution of spin-labeled phospholipids in the erythrocyte membrane: Relation to shape changes. Proc. Natl. Acad. Sci., USA 1984;81:3751-3755. | |
| | | Tracy P, Peterson J, Nesheim M, McDuffie F, Mann K. Interaction of coagulation factor V and factor Va with platelets. J. Biol. Chem. 1979;254:10345. | |
| | | Swords NA, Tracy PB, Mann KG. Intact Platelet Membranes, Not Platelet-Released Microvesicles, Support the Procoagulant Activity of Adherent Platelets. Arterioscler. Thromb. 1993;13(11):1613-1622. | |
| | | Ahmad SS, Rawala-Sheikh R, Ashby B, Walsh PN. Platelet receptor-mediated factor X activation by factor IXa: High-affinity factor IXa receptors induced by factor VIII are deficient on platelets in Scott syndrome. J. Clin. Invest. 1989;84:824-828. | |
| | | Comfurius P, Bervers EM, Zwaal RFA. Enzymatic synthesis of phosphatidylserine on small scale by use of a one-phase system. J. Lipid Res. 1990;31:1719-1721. | |

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| | | | |
| | | Pusey M, Mayer L, Wei G, Bloomfield V, Nelsestuen G. Kinetic and Hydrodynamic Analysis of Blood Clotting Factor V-Membrane Binding. Biochemistry 1982;21:5262-5269. | |
| | | Abbott A, Nelsestuen G. Association of a Protein with Membrane Vesicles at the Collisional Limit: Studies with Blood Coagulation Factor Va Light Chain Also Suggest Major Differences between Small and Large Unilamellar Vesicles. Biochemistry 1987;26:7994-8003. | |
| | | Bloom JW. The interaction of rDNA factor VIII, factor VIII _{des} -797-1562 and factor VIII _{des} -797-1562 derived peptides with phospholipid. Throm. Res. 1987;48:439-448. | |
| | | Epand RM, Stevenson C, Bruins R, Schram V, Glaser M. The chirality of phosphatidylserine and the activation of protein kinase C. Biochemistry 1998;37(35):12068-73. | |
| | | Berden JA, Barker RW, Radda GK. NMR studies on phospholipid bilayers. Some factors affecting lipid distribution. Biochim. Biophys. Acta 1975;375(2):186-208. | |
| | | Barsukov LI, Victorov AV, Vasilenko IA, Evstigneeva RP, Bergelson LD. Investigation of the inside-outside distribution, intermembrane exchange and transbilayer movement of phospholipids in sonicated vesicles by shift reagent NMR. Biochim. Biophys. Acta 1980;598(1):153-68. | |
| | | Litman BJ. Determination of molecular asymmetry in the phosphatidylethanolamine surface distribution in mixed phospholipid vesicles. Biochemistry 1974;13(14):2844-8. | |
| | | Koynova RD, Tenchov BG. Effect of ion concentration on phosphatidylethanolamine distribution in mixed vesicles. Biochim. Biophys. Acta 1983;727(2):351-6. | |
| | | Lentz BR, Litman BJ. Effect of head group on phospholipid mixing in small, unilamellar vesicles: mixtures of dimyristoylphosphatidylcholine and dimyristoylphosphatidylethanolamine. Biochemistry 1978;17(25):5537-43. | |

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| | | Nordlund JR, Schmidt CF, Dicken SN, Thompson TE. Transbilayer distribution of phosphatidylethanolamine in large and small unilamellar vesicles. Biochemistry 1981;20(11):3237-41. | |
| | | Tait JF, Gibson D. Phospholipid binding of annexin V: effects of calcium and membrane phosphatidylserine content. Arch. Biochem. Biophys. 1992;298(1):187-91. | |
| | | Pigault C, Follenius-Wund A, Schmutz M, Freyssinet JM, Brisson A. Formation of two-dimensional arrays of annexin V on phosphatidylserine-containing liposomes. J. Mol. Biol. 1994;236(1):199-208. | |
| | | Koopman G, Reutelingsperger CP, Kuijten GA, Keehnen RM, Pals ST, van Oers MH. Annexin V for flow cytometric detection of phosphatidylserine expression on B cells undergoing apoptosis. Blood 1994;84(5):1415-20. | |
| | | Connor J, Bucana C, Fidler IJ, Schroit AJ. Differentiation-dependent expression of phosphatidylserine in mammalian plasma membranes: Quantitative assessment of outer-leaflet lipid by prothrombinase complex formation. Proc. Natl. Acad. Sci. USA 1989;86:3184-3188. | |
| | | Poste G, Papahadjopoulos D. Lipid vesicles as carriers for introducing materials into cultured cells: influence of vesicle lipid composition on mechanism(s) of vesicle incorporation into cells. Proc. Natl. Acad. Sci. U. S. A. 1976;73(5):1603-7. | |
| | | Batzri S, Korn ED. Interaction of phospholipid vesicles with cells. Endocytosis and fusion as alternate mechanisms for the uptake of lipid-soluble and water-soluble molecules. J. Cell Biol. 1975;66(3):621-34. | |
| | | Chang CP, Zhao J, Wiedmer T, Sims PJ. Contribution of platelet microparticle formation and granule secretion to the transbilayer migration of phosphatidylserine. J. Biol. Chem. 1993;268:7171-7178. | |
| | | McIntyre JC, Sleight RG. Fluorescence Assay for Phospholipid Membrane Assymetry. Biochemistry 1991;30:11819-11827. | |
| | | Lawler J, Hynes RO. An integrin receptor on normal and thrombasthenic platelets that binds thrombospondin. Blood 1989;74(6):2022-7. | |

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|-----------------------------------|--------------------------|--|----------------|
| | | Bervers E, Wiedmer T, Comfurius P, Shattil S, Weiss H, Zwaal R, et al. Defective Ca ²⁺ -Induced Microvesiculation and Deficient Expression of Procoagulant Activity in Erythrocytes From a Patient With a Bleeding Disorder: A Study of the Red Blood Cells of Scott Syndrome. Blood 1992;79:380-388. | |
| | | Jain MK, Rogers J, Marecek JF, Ramirez F, Eibl H. Effect of the structure of phospholipid on the kinetics of intravesicle scooting of phospholipase A2. Biochim. Biophys. Acta 1986;860(3):462-74. | |
| | | Kim DH, Azuma N, Tanaka H, Kanno C. Structures of the N-linked sugar chains in the PAS-6 glycoprotein from the bovine milk fat globule membrane. Glycoconjugate Journal 1998; 15:361-369. | |
| | | Shi J, Gilbert GE. Lactadherin inhibits enzyme complexes of blood coagulation by competing for phospholipid binding sites. Blood December 2002;100(11):262a, American Society of Hematology Abstract (1 page). | |
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